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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Attached continuation sheet:

Amendments (from 3)

Applicant has filed a Claim set on 1/12/2012 which does not contain any amendments to the Claims rejected in the Office Action mailed 10/19/2011. Accordingly, the Claims filed 1/12/2012 will be entered but does not place the Application in condition for allowance for the reasons discussed below under 'Request for Reconsideration'.

Request for Reconsideration/Other (from 13)

Applicant's argues that, individually, none of the applied references (Song, Klokke-Bethke, Talalay and Graf) teach the limitations recited in independent Claim 1 and 54 (Remarks, page 9 – 10, bridging paragraph).

The Examiner has previously responded to this argument in the Office Action mailed 10/19/2011 (pages 20 – 23) and is of record. In brief, the Examiner agrees with Applicant that none of the references cited in the applied 103(a) rejection teach all of the limitations of independent Claims 1 and 54.

Applicant notes that the Office now requires four references to make the present [103a] rejection of independent Claims 1 and 54 (Remarks, page 10, 2nd paragraph).

In response to Applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

Applicant argues "the Office ... states that it is *prima facie* obvious to modify the teaching of Song by applying the drying method of Klokckers-Bethke based on the motivation of minimizing exposure to an oxidizing environment. While the drying method of Klokckers-Bethke might reduce exposure to oxygen, it does not completely eliminate it (Remarks, page 11, final paragraph).

This argument is not found to be persuasive because the motivation to combine Song with Klokckers-Bethke does not require elimination of oxygen only that it would help to minimize exposure to oxygen, a feature explicitly suggested by Song. Song, teaches the desirability of limiting exposure of the coated medical device to an oxidizing atmosphere and explicitly encourages both maintaining the coated device in an inert atmosphere of nitrogen during the course of its formation and to place the coated medical device into packaging (i.e. a receptacle) that has been evacuated or into which an inert gas has been introduced (Song, p [0046] – [0048] and page 13, 1st paragraph, Office Action mailed 10/19/2011).

Applicant argues even if such a combination were made (i.e. Song with Klokke-Bethke), the Office admits that the combination of Song with Klokke-Bethke fails to teach the required limitation of removing the solvent by isothermal drying as recited in claim 1, step (d) (Remarks, pages 11 – 12, bridging paragraph).

In response the Examiner, as noted by Applicant, admits that said combination of references fails to teach the feature of isothermal drying recited in instant Claim 1. Klokke-Bethke teaches an alternative solvent removal (i.e. drying) method, freeze-drying (i.e. lyophilization). Talalay teaches a method consistent with 'isothermal drying', and is considered to be a functional equivalent of lyophilization (KSR Exemplary rationale B, as discussed on page 14, 2nd paragraph of the Office Action mailed 10/19/2011).

Applicant argues that a person skilled in the art would never have made such a substitution (isothermal drying for lyophilization) for the following reasons (Remarks, page 12, 2nd paragraph through page 14, 1st paragraph).

First, Applicant argues the motivation offered by the Office to replace the drying method of Klokke-Bethke with that of Talalay, i.e. to ensure a longer shelf life of the material contained therein, is already solved by Klokke-Bethke. Therefore, a person skilled in the art would not be motivated to resolve a non-existing "problem" because the problem had already been solved (Remarks, page 12, 3rd paragraph).

This argument is not found to be persuasive because it is obvious to substitute one known drying method (lyophilization) for an alternative known drying method (isothermal drying) if the results are predictable (MPEP 2141, KSR Exemplary Rationale B).

Second, Applicant argues that the drying process of Talalay uses a stream of gently warmed air blown over the solution of the containers which is eventually followed by filling the chambers with an inert gas such as nitrogen while the containers are sealed. Applicant, notes that air contains oxygen and that exposure of the solutions to air would increase exposure of the coated medical device to an oxidizing (i.e. oxygen containing) atmosphere which runs contrary to the stated motivation for combining Song and Klokke-Bethke (Remarks, pages 12 – 13, bridging paragraph).

This argument is not found to be persuasive because the primary reference, Song, as discussed above, explicitly suggests exposure to nitrogen or another inert gas and warns against an oxidizing atmosphere. Further, Klokke-Bethke places the solution in a nitrogen atmosphere prior to drying by lyophilization (page 9, 1st paragraph, Office Action mailed 10/19/2011). Thus each reference clearly teaches an inert atmosphere and minimizing exposure to oxygen.

Further, in response to applicant's argument that Talalay's teaching of a gentle stream of warm air is contrary to the stated motivation for combining Song and Klokke-Bethke, the test for obviousness is not whether the features of a secondary reference (Talalay) may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the

references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In the present case, one of ordinary skill would reasonably adapt the process of isothermal drying as an alternative known drying technique, however, in view of Song would know that oxidizing atmospheres are contraindicated and would reasonably modify the drying procedure of Talalay to ensure a non-oxidizing atmosphere (consistent with Song and Talalay) by employing a gentle stream of a warmed inert gas, e.g. nitrogen, in lieu of air.

Third, Applicant argues that Talalay does not describe an isothermal drying step as required by the present invention. The Office has correctly stated that the isothermal drying step is disclosed on page 20, lines 6-25 of the present specification where it is stated that the process is carried out under reduced pressure and at a defined (constant) temperature. Talalay does not, however, specifically describe these conditions and therefore does not describe an isothermal drying step at all. Talalay only describes that in step 1 (of 3 drying steps), "the temperature is kept to approximately 65° C or below". See Talalay, column 3, lines 56-58. No defined (constant) temperature is thereby taught or suggested (Remarks, page 13, 2nd paragraph).

This argument is not found to be persuasive because, first, the teaching by Talalay of approximately 65° C or below allows for the drying in step 1 of Talalay to be reasonably construed as a constant temperature (approximately 65° C). Second, step (d) of

instant Claim 1 requires that isothermal drying be applied at the start of the drying process, which is consistent with a step 1 of Talalay (which precedes steps 2 and 3). Instant Claim 1 uses open comprising language and thus does not exclude additional drying steps which may or may not fall within the scope of isothermal.

Applicant argues that Klokke-Bethke does not teach or suggest that a quantitative deposition of the coating substance on the device is increased as is summarized by Fig. 9 of the present application (Remarks, page 15, 1st paragraph).

In response the Examiner agrees with Applicant, but notes that the applied rejection combines Song with Klokke-Bethke to render obvious this limitation.

Applicants argues, again, that none of Song, Klokke-Bethke, Talalay and Graft contain teach or suggest, either alone or in combination, all the features of independent claim 1 of the present invention (Remarks, page 14, 2nd paragraph).

Applicant argues that because each of Song, Klokke-Bethke, Talalay and Graft fail to teach or suggest the limitations recited in independent Claim 1 and 54, any combination of Song, Klokke-Bethke, Talalay and Graft, to the extent proper, could also not render independent claims 1 and 54 obvious (Remarks, page 15, 3rd paragraph).

In response, the Examiner, as set forth in the 103(a) rejection applied in the Office Action mailed 10/19/2011, has also noted that none of the references individually teach each of the limitations recited in independent Claims 1 and 54. Accordingly, the

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Examiner has rejected independent Claims 1 and 54, for the reasons set forth in said 103(a) rejection, using a combination of said references.

/DENNIS HEYER/

Examiner, Art Unit 1628

/Timothy P Thomas/

Primary Examiner, Art Unit 1628